

ASSEMBLY BILL

No. 170

Introduced by Assembly Member Gatto

January 22, 2015

An act to amend Section 125000 of, and to add Section 125003 to, the Health and Safety Code, relating to newborn screening.

LEGISLATIVE COUNSEL'S DIGEST

AB 170, as introduced, Gatto. Newborn screening: genetic diseases: blood samples collected.

Existing law requires the State Department of Public Health to establish a program for the development, provision, and evaluation of genetic disease testing, and the program is required to provide genetic screening and followup services for persons who have the screening. The program includes statewide screening of newborn children through the collection of blood samples, unless the parent or guardian objects on the grounds of religious beliefs or practices.

This bill would authorize a parent or guardian of a minor child and the newborn child, once he or she is legally an adult, to request that the department destroy, not use for research purposes, or both, the blood sample, and the department would be required to do so. The bill would also require the department to prepare and provide informational materials, to be distributed as specified, regarding the newborn child blood sample collected pursuant to the program that includes, but is not limited to, information on storage, retention, and use of the blood sample, and the right of specified persons to request that the blood sample be destroyed, not used for research purposes, or both.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 125000 of the Health and Safety Code
2 is amended to read:

3 125000. (a) It is the policy of the State of California to make
4 every effort to detect, as early as possible, phenylketonuria and
5 other preventable heritable or congenital disorders leading to
6 intellectual disability or physical defects.

7 The department shall establish a genetic disease unit, that shall
8 coordinate all programs of the department in the area of genetic
9 disease. The unit shall promote a statewide program of information,
10 testing, and counseling services and shall have the responsibility
11 of designating tests and regulations to be used in executing this
12 program.

13 The information, tests, and counseling for children shall be in
14 accordance with accepted medical practices and shall be
15 administered to each child born in California once the department
16 has established appropriate regulations and testing methods. The
17 information, tests, and counseling for pregnant women shall be in
18 accordance with accepted medical practices and shall be offered
19 to each pregnant woman in California once the department has
20 established appropriate regulations and testing methods. These
21 regulations shall follow the standards and principles specified in
22 Section 124980. The department may provide laboratory testing
23 facilities or contract with any laboratory that it deems qualified to
24 conduct tests required under this section. However, notwithstanding
25 former Section 125005, provision of laboratory testing facilities
26 by the department shall be contingent upon the provision of funding
27 therefor by specific appropriation to the Genetic Disease Testing
28 Fund enacted by the Legislature. If moneys appropriated for
29 purposes of this section are not authorized for expenditure to
30 provide laboratory facilities, the department may nevertheless
31 contract to provide laboratory testing services pursuant to this
32 section and shall perform laboratory services, including, but not
33 limited to, quality control, confirmatory, and emergency testing,
34 necessary to ensure the objectives of this program.

35 (b) The department shall charge a fee for any tests performed
36 pursuant to this section. The amount of the fee shall be established
37 and periodically adjusted by the director in order to meet the costs
38 of this section.

1 (c) The department shall inform all hospitals or physicians and
2 surgeons, or both, of required regulations and tests and may alter
3 or withdraw any of these requirements whenever sound medical
4 practice so indicates. To the extent practicable, the department
5 shall provide notice to hospitals and other payers in advance of an
6 increase in the fees charged for the program.

7 (d) This section shall not apply if a parent or guardian of the
8 newborn child objects to a test on the ground that the test conflicts
9 with his or her religious beliefs or practices.

10 (e) The genetic disease unit is authorized to make grants or
11 contracts or payments to vendors approved by the department for
12 all of the following:

13 (1) Testing and counseling services.

14 (2) Demonstration projects to determine the desirability and
15 feasibility of additional tests or new genetic services.

16 (3) To initiate the development of genetic services in areas of
17 need.

18 (4) To purchase or provide genetic services from any sums as
19 are appropriated for this purpose.

20 (f) The genetic disease unit shall evaluate and prepare
21 recommendations on the implementation of tests for the detection
22 of hereditary and congenital diseases, including, but not limited
23 to, biotinidase deficiency and cystic fibrosis. The genetic disease
24 unit shall also evaluate and prepare recommendations on the
25 availability and effectiveness of preventative followup
26 interventions, including the use of specialized medically necessary
27 dietary products.

28 It is the intent of the Legislature that funds for the support of the
29 evaluations and recommendations required pursuant to this
30 subdivision, and for the activities authorized pursuant to
31 subdivision (e), shall be provided in the annual Budget Act
32 appropriation from the Genetic Disease Testing Fund.

33 (g) Health care providers that contract with a prepaid group
34 practice health care service plan that annually has at least 20,000
35 births among its membership, may provide, without contracting
36 with the department, any or all of the testing and counseling
37 services required to be provided under this section or the
38 regulations adopted pursuant thereto, if the services meet the
39 quality standards and adhere to the regulations established by the
40 department and the plan pays that portion of a fee established under

1 this section that is directly attributable to the department's cost of
2 administering the testing or counseling service and to any required
3 testing or counseling services provided by the state for plan
4 members. The payment by the plan, as provided in this subdivision,
5 shall be deemed to fulfill any obligation the provider or the
6 provider's patient may have to the department to pay a fee in
7 connection with the testing or counseling service.

8 (h) The department may appoint experts in the area of genetic
9 screening, including, but not limited to, cytogenetics, molecular
10 biology, prenatal, specimen collection, and ultrasound to provide
11 expert advice and opinion on the interpretation and enforcement
12 of regulations adopted pursuant to this section. These experts shall
13 be designated agents of the state with respect to their assignments.
14 These experts shall receive no salary, but shall be reimbursed for
15 expenses associated with the purposes of this section. All expenses
16 of the experts for the purposes of this section shall be paid from
17 the Genetic Disease Testing Fund.

18 (i) *A parent or legal guardian of a minor may request the*
19 *department to destroy, not use for research purposes, or both, the*
20 *blood sample of the minor collected as a newborn, and the*
21 *department shall do so.*

22 (j) *An individual who is at least 18 years of age may request*
23 *the department to destroy, not use for research purposes, or both,*
24 *his or her blood sample that was collected, and the department*
25 *shall do so.*

26 SEC. 2. Section 125003 is added to the Health and Safety Code,
27 to read:

28 125003. (a) The department shall prepare and provide
29 informational materials regarding newborn child blood samples
30 collected pursuant to this article that include, but are not limited
31 to, all of the following:

32 (1) Storage, retention, and use of the blood sample.

33 (2) The parent or legal guardian's right to request that his or her
34 minor child's blood sample be destroyed, not used for research
35 purposes, or both, and the information necessary to make that
36 request.

37 (3) The right of an individual who is at least 18 years of age to
38 request that his or her blood sample be destroyed, not used for
39 research purposes, or both, and the information necessary to make
40 that request.

1 (b) The informational materials prepared and provided by the
2 department shall be distributed as follows:

3 (1) Every birth attendant engaged in providing perinatal care
4 shall provide a pregnant woman, prior to the estimated date of
5 delivery, with a copy of the informational materials provided by
6 the department.

7 (2) Every perinatal licensed health facility shall provide each
8 pregnant woman admitted for delivery with a copy of the
9 informational materials provided by the department, prior to
10 collection of the blood sample, if that information has not been
11 provided pursuant to paragraph (1).

12 (3) The local registrar of births shall provide a copy of the
13 informational material provided by the department to each person
14 registering the birth of a newborn that occurred outside of a
15 perinatal licensed health facility when the newborn was not
16 admitted to a perinatal licensed health facility within the first 30
17 days of age. The local health officer and the department shall be
18 notified of each of these registrations by the local registrar.

19 (c) For the purposes of this section, the following terms shall
20 have the following meanings:

21 (1) "Birth attendant" means a person licensed or certified by
22 the state to provide maternity care and to deliver pregnant women
23 or to practice medicine.

24 (2) "Perinatal licensed health facility" means a health facility
25 licensed by the state and approved to provide perinatal, delivery,
26 newborn intensive care, newborn nursery, or pediatric services.